

Oath/Declaration

The oath/declaration has been objected to for failure to specifically identify at least one error in the patent. Applicants enclose herewith a substitute declaration that reorders the content and rennumbers the pages of the declaration to clarify that the inventors read and agreed to the statements contained therein.

The Rejection of Claims 1-24 Under 35 U.S.C. § 112, First Paragraph

Claims 1-24 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

To comply with the written description requirement, the description must clearly allow persons of ordinary skill in the art to recognize that applicants invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). The subject matter of the claim need not be described literally (*in haec verba*) for the disclosure to satisfy the written description requirement. See MPEP § 2163.02. Applicants' disclosure clearly conveys to one of skill in the art that applicants had possession of the claimed invention at the time of filing.

The Office Action asserts five specific reasons why the claims lack adequate written description. Each will be discussed in turn.

A. The Office Action asserts that the claims are not adequately described because although the specification discloses that the mammalian INGAP protein and portions thereof are involved in islet cell neogenesis, it does not disclose how INGAP is involved in islet cell neogenesis. The Office Action alleges that "the specification does not clearly set forth how the polypeptide is

involved in islet cell neogenesis.” (Paper 9, page 5, lines 9-10.) The written description requirement, however, does not require that applicants teach how claimed nucleotide sequences exert a physiological effect. Rather, the written description requirement is met if the specification conveys to those of skill in the art that applicants had possession of the claimed invention. Possession can be demonstrated by disclosing characteristics of the claimed invention. MPEP § 2163 outlines such characteristics:

Complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The claims are directed to DNA molecules encoding a particular, recited amino acid sequence (SEQ ID NO: 2). The specification teaches the complete amino acid sequence and the nucleotide sequence from human and hamster that encodes the complete amino acid sequence (SEQ ID NO: 1). The sequences disclosed thus provide a complete structural and functional description as required by MPEP § 2163. A mechanism of action for the encoded polypeptide is simply not required to adequately describe a nucleotide sequence.

B. The Office Action asserts that claims 1, 12, and 17 are not adequately described for failing to recite a function of the polypeptide. The Office Action alleges “the claims recite an isolated DNA molecule encoding a mammalian islet cell neogenesis associated protein (INGAP) and the specific sequence with no limitation to the function of the polypeptide.” (Paper 9, page 5, lines 11-13.) Because claims 1, 12, and 17 are described by the sequence (*i.e.*, complete structure) of the encoded protein, the function of the encoded protein is not required. All protein molecules which have the claimed amino acid sequence are useful and need not be limited to a function of the polypeptide.

C. The Office Action also alleges that the specification fails to meet the written description requirement for failing to describe representative species. The Office Action asserts that “the application only describes an INGAP set forth in SEQ ID NOs: 1 and 2 (DNA and the encoding protein), therefore, the specification fails to describe representative species.” (Paper 9, page 5, lines 13-15.) MPEP § 2163 states: “Satisfactory disclosure of a ‘representative number’ depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” Because the claimed genus of DNA molecules is limited to those that encode a particular, recited amino acid sequence, the genus does not require disclosure of a large number of species. MPEP § 2163 further sets forth:

Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

Thus one of skill in the art would readily recognize that applications were in possession of the necessary common attributes possessed by the members of the genus of nucleotide sequences encoding mammalian INGAP having the amino acid sequence of SEQ ID NO: 2.

D. The Office Action also alleges that the claims lack adequate written description because they recite “portions” of mammalian INGAP. The Office Action alleges, “[C]laims are directed to portions of the claimed protein (see for example claims 17 and 24), therefore, the claims are drawn to a large variable genus of polypeptides for which the activity has not been described or recited in the claims.” (Paper 9, page 5, lines 15-17.) Applicants respectfully note that the claims are directed to polynucleotides, not polypeptides. Claim 17 is directed to antisense

constructs and claim 24 is directed to portions of at least 30 contiguous nucleotides. Such polynucleotides are useful as probes or anti-sense agents regardless of their protein coding capacity. Their function depends on DNA hybridization. Any of the claimed portions would thus be useful irrespective of the activity of the encoded polypeptides. Withdrawal of this rejection to claims 17 and 24 is respectfully requested.

E. The Office Action asserts that claim 19 lacks adequate written description because it is directed to a fragment of the INGAP nucleotide sequence “and the specification does [not] disclose if these nucleotides encode the claimed protein.” (Paper 9, page 5, lines 18-19.) Claim 19 is not directed to fragments as alleged. It is directed to a DNA molecule encoding the full INGAP polypeptide as shown in SEQ ID NO: 2. Such a claim construction is mandated by the dependence of claim 19 on claim 1. Claim 1 recites a DNA molecule encoding the full INGAP polypeptide as shown in SEQ ID NO: 2. Upon properly construing claim 19 one must conclude that the DNA molecule of claim 19 encodes the INGAP protein. Withdrawal of this rejection to claim 19 is respectfully requested.

The Rejection of Claims 17 and 24 Under 35 U.S.C. § 251

Claims 17 and 24 have been rejected under 35 U.S.C. § 251 as improperly attempting to recapture subject matter surrendered in the application for the patent upon which the present reissue is based. Applicants respectfully traverse.

The MPEP sets forth a two-step test for determining if reissue claims have attempted to recapture previously canceled subject matter. Section 1412.02 citing *Clement*, 131 F.3d at 1468-69. The first step is to “review each claim for the presence of broadening, as compared with the scope of the claims of the patent to be reissued.” Claim 17 has been amended in the reissue

application to recite “a nucleotide sequence which encodes all or a portion of a protein as shown in SEQ ID NO: 2” in place of “a nucleotide sequence consisting of a mammalian INGAP gene wherein the gene encodes a protein as shown in SEQ ID NO: 2.” The scope of claim 17 has been enlarged.

The second step is to “determine whether the broader aspects of the reissue claims relate to surrendered subject matter.” Subject matter is surrendered if “the limitation now being omitted or broadened in the present reissue was originally presented/argued/stated in the original application to make the claims allowable over a rejection or objection made in the original application.” MPEP § 1412.02.

Patent claim 17, as originally filed, recited “a nucleotide sequence consisting of a mammalian INGAP gene.” Thus it recited the complete gene. The claim was amended to overcome an enablement rejection which alleged that the originally filed claim was overly broad for reciting “any nucleic acid encoding any INGAP from any source.” (Office Action dated September 18, 1997, page 5, lines 11-12.) The amendment added the phrase “wherein the gene encodes a protein as shown in SEQ ID NO: 2.” This amendment limited the claim to a specific mammalian INGAP nucleotide sequence. The amendment did not change the size of the recited nucleotide sequence.

Reissue claim 17 recites a nucleotide sequence that encodes “all or a portion” of a mammalian INGAP protein as shown in SEQ ID NO: 2. The Patent Office asserts that patentees surrendered such subject matter (*i.e.*, the portion) during prosecution of the underlying patent application. However, applicants did not surrender the scope of their claim relating to portions of the mammalian INGAP nucleotide sequence. Patentees stated: “The rejection also asserted that claims which did not specify a sequence were overly broad. Applicants have, as suggested,

recited a sequence in each of the independent claims.” (Response dated November 25, 1997, page 3, lines 23-24.) Thus applicants did not surrender “portions” in the claim that issued as claim 17 in U.S. Patent 5,840,531. Since patentees did not surrender portions, reissue claim 17 does not contravene 35 U.S.C. § 251. Withdrawal of this rejection to claim 17 is respectfully requested.

Claim 24 fails to meet the first prong of the recapture analysis because it does not broaden the claims of U.S. Patent 5,840,531. Claim 24 is a new claim which is dependent upon, and therefore narrower than, claim 12 of issued patent 5,840,531. Thus the rejection of claim 24 should be withdrawn because claim 24 fails the first prong of the test for recapture. Moreover, even if, *arguendo*, claim 24 were found to be broader than claims of the issued patent, the Patent Office has failed to allege how claim 24 attempts to recapture previously surrendered subject matter. Broadening *per se* is not prohibited in reissues filed within 2 years of a patent’s grant. See U.S.C. § 251, paragraph 4. Withdrawal of this rejection of claim 24 is respectfully requested.

The Rejection of Claims 1-24 under 35 U.S.C. § 112, Second Paragraph

Claims 1-24 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse. The Office Action specifically asserts five reasons why the claims stand rejected. Each will be discussed in turn.

A. The Office Action asserts that claim 1 is indefinite for reciting INGAP protein. The Office Action alleges that “the recitation of ‘INGAP’ alone is sufficient as it means ‘islet cell neogenesis protein’.” (Paper 9, page 8, lines 5-6.) Applicants have amended claim 1 and

dependent claims 15, 16, and 18 as suggested in the Office Action. Claim 2 is similarly rejected, however it does not recite “INGAP protein.” Applicants’ preliminary amendment filed November 22, 2000, deleted the offending phrase. Thus the rejection is rendered moot. Withdrawal of this rejection to claims 1, 2, 15, 16, and 18 is respectfully requested.

B. The Office Action asserts that claim 5 is indefinite for reciting “EBNA” without the spelled out meaning of the acronym. Claim 5 has been amended to recite the “Epstein Barr Nuclear Antigen-Histidine (EBNA-His)” to spell out the words abbreviated by EBNA-His. Thus the rejection is rendered moot. Withdrawal of this rejection to claim 5 is respectfully requested.

C. The Office Action asserts that claim 8 is indefinite because of inappropriate spacing in the recitation “cos7,African.” The claim has been amended to insert a space between the “,” and “African.” Thus the rejection is rendered moot. Withdrawal of this rejection to claim 8 is respectfully requested.

D. The Office Action asserts that claim 10 is indefinite because it recites a sequence but does not indicate what type of sequence is intended by the claim. The Office Action alleges that “the claim recites ‘the nucleotide probe of claim 9 wherein the sequence encoding...’ and there is no reference to what sequence.” (Paper 9, page 8, lines 15-16.) Claim 10 has been amended to recite “wherein the nucleotide sequence encoding” as suggested in the Office Action. Thus the rejection is rendered moot. Withdrawal of this rejection to claim 10 is respectfully requested.

E. The Office Action asserts that claims 11 and 14 are indefinite for reciting “detectable moiety” because it is unclear what “detectable moiety” the claims are referring to. The standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870 (Fed. Cir. 1993).

The specification clearly teaches the meaning of detectable moieties. The specification discloses: "The probe may be labeled with any detectable moiety known in the art, including radiolabels, fluorescent labels, enzymes, etc." (Column 6, lines 50-52.) Thus the claims read in light of the specification are definite as to what "detectable moieties" mean. Withdrawal of this rejection to claims 11 and 14 is respectfully requested.

Provisional Double Patenting Rejection of Claims 1-24

Claims 1-24 are provisionally rejected as unpatentable over claims 1-49 of co-pending Application No. 09/659,379. Applicants respectfully traverse.

The Office Action asserts that the claims are obvious variants of claims 1-49 of co-pending Application No. 09/659,379 because:

[C]laims in the copending application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the present application is directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence).

Paper 9, page 9, line 18 through page 10, line 1.

The Patent Office should apply a two-way obviousness test to the claims of the instant application and the claims of co-pending Ser. No. 09/659,379. MPEP § 804 sets forth that the two-way obviousness test must be applied when the applicant could not have filed the claims in a single application *and* there is administrative delay. *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998.) The instant application and the application cited in the rejection, Ser. No. 09/659,379, meet both these criteria. First, these two applications could not have been filed together. The instant application is the first-filed application. It bears a priority date of February 22, 1995. It

discloses INGAP. Ser. No. 09/659,379 discloses high-level expression of INGAP. At the time of the application filings on INGAP (February 22, 1995 and November 11, 1995,) applicants had not yet invented high-level expression of INGAP. High-level expression was not filed until October 30, 1996. Thus the two applications could not have been filed simultaneously.

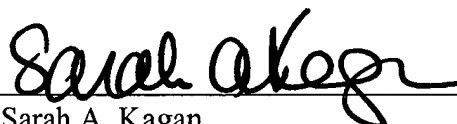
Second, the Patent Office controlled the rate of prosecution of the applications leading to the instant application. The Patent Office controlled the rates of prosecution because the later-filed species claims (Ser. No. 08/909,725) issued before the claims for the genus in the earlier filed application (Ser. No. 08/709,662). Applicants did not voluntarily present its genus claims for examination after it let its species claims issue. Applicants filed its genus claims first and they happened to issue after the species claims. Applicants made no “considered election to postpone acquisition of the broader” patent. See *Pierce v. Allen B. DuMont Laboratories, Inc.*, 297 F.2d 323 (3rd. Cir. 1961). Applicant simply did not have complete control over rates of progress through the Patent Office. See *In re Braat*, F.2d 589 (Fed. Cir. 1991). Thus a two-way test is appropriate.

When making a two-way obviousness determination, it is necessary to apply the obviousness analysis reciprocally. It is respectfully submitted that the claims of the later invention of Serial No. 09/659,379 would not have been obvious in view of the claims of the earlier invention of the instant application. Serial No. 09/659,379 discloses that INGAP can be expressed at high levels if the signal peptide coding sequence of the INGAP nucleotide sequence is removed. It would not have been obvious to exclude the nucleotides encoding the signal sequence of the full-length INGAP coding sequence based on the claims of the instant application. The claims of the instant application neither teach nor suggest this unpredictable result. Thus the double patenting rejection of claims 1-24 should be withdrawn.

The Office Action also alleges that "the present application and copending application both claim probes, primers and have claims directed to antisense strands which would render each other obvious." (Page 10, lines 1-3.) Copending application 09/659,379 does not claim probes or antisense strands at all. It claims pairs of primers. The pairs of primers are made up of first and second oligonucleotide primers that hybridize to the 5' end of the nucleotide sequence of mature human INGAP and the 3' end of the nucleotide sequence of human INGAP. The instant application, in contrast, does not claim any primer pairs. It claims probes or antisense constructs. A probe or an antisense construct for INGAP is not obvious over pairs of oligonucleotide primers for amplifying mature INGAP.

Withdrawal of the double patenting rejection of claims 1-24 is respectfully requested.

Respectfully submitted,

By: 
Sarah A. Kagan
Reg. No. 32,141

Dated: February 26, 2002

Banner & Witcoff, LTD.
Eleventh Floor
1001 G Street, N.W.
Washington, D. C. 20001-4597
(202) 508-9100

Status of Claims and Support for Claim Changes

Status of Claims

Patent claims 1-19 and newly added claims 20-24 are pending in the application.

Support for Claim Changes

Claims 1, 15, 16, and 18 have each been amended to recite “INGAP” instead of “INGAP protein.” The amendment merely clarifies the claim such that it does not recite “islet cell neogenesis protein protein.” The amendment also does not narrow the scope of the claim.

Claim 5 has been amended to recite “Epstein-Barr nuclear antigen-Histidine” instead of “EBNA-His.” The amendment merely clarifies the claim by providing the spelled-out meaning of the well-known acronym EBNA-His. The amendment also does not narrow the scope of the claim.

Claim 8 has also been amended to recite “cos7, African” instead of “cos7,African.” The amendment merely clarifies the claim by inserting a space between the “,” and “African.” The amendment does not introduce new matter into the claim or narrow the scope of the claim.

Claim 10 has been amended to recite “the nucleotide sequence encoding a mammalian INGAP” instead of “the sequence encoding a mammalian INGAP.” The amendment merely clarifies which type of sequence is referred to in the claim and does not narrow the scope of the claim.